THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: S. Jayaraman

Attorney Docket No.: 795-A03-004

Application No.: To be Assigned

Group Art Unit:

Filed: Herewith

Examiner:

For: RATIONALLY DESIGNED THERAPEUTIC INTRAVASCULAR IMPLANT

COATING

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.56

Commissioner for Patents Alexandria, VA 22313

Sir:

In accordance with the duty of disclosure provisions of C.F.R. § 1.56, there is hereby provided certain information, which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

A revised Form PTO/SB/08 listing all patents, publications, applications, or other information submitted for consideration is enclosed. Copies of the listed U.S. Patents and Published U.S. Patent applications are not being submitted pursuant to the USPTO's wavier of the requirement of 37 C.F.R. § 1.98(a)(2)(i). Enclosures accompanying this Information Disclosure Statement are: (a) copies of the cited foreign references (b) copies of cited articles.

No admission is made that the information cited in this Statement is, or is considered to be prior art, material to patentability nor a representation that a search has been made.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b) before the latter of three months after the U.S. patent application filing date or the first Office Action on the merits. Accordingly, no fee or certification is required.

Dated: 10/09/2003

Respectfully submitted,

Paul D. Bianco (Reg. No. 43,500)

Attorney for Applicant

Fleit, Kain, Gibbons, Gutman, Bongini & Bianco P.L.

601 Brickell Key Drive

Suite 404

Miami, Florida 33131 305-931-9620 (telephone)

PTO/SB/08A (10-96) Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. Department of Commerce

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute fo	or form 1	449A/PTO					Complete If Known				
INF		IN A	N DISCL AN APPL nany shee	ICAT	ION						
	-		Ū				Application	Number			
							Filing Date				
•							First Name	d Inventor	S. Jav	yaramna	
							Group Art U	nit			
	_					•	Examiner Na	ame			
Sheet		4		of		8	Attorney Do	cket Number	795-4	A03-004	
						U.S. PATENT DO	CUMENTS			<u> </u>	
Examiner Initials	Cite No. ¹	L	J.S. Patent D Number	ocument Kind ((if kno		Name of Patentee o Cited Docu	r Applicant of	Date of Public of Cited Docu MM-DD-Y	ment	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	EA	2001/0	0029351	A1		Falotico et al.		10-11-20	01		
	EB	2002/0	0016625	A1		Falotico et al.		02-07-20	02		
	EC	2002/0	0013335	A1		Azrola et al.		01-31-20	02		
	ED	2002/0	0007215	A 1		Falotico et al.		01-17-20	02		
	EE 2002/0007214 A1				Falotico et al.		01-17-20				
	EF	2002/0	0007213	A 1		Falotico et al.		01-17-20			
	EG	2002/0	0005206	A 1		Falotico et al.	01-17-20	01-17-2002			
	EH	2003/0	0086957	A 1		Huges		05-08-20	03		
		<u> </u>									
	ļ. 										
		ļ					· · · · · · · · · · · · · · · · · · ·				
		ļ									
	1_				_			1			
	<u> </u>	ļ									
	<u> </u>	<u> </u>			_						
	<u> </u>	<u> </u>	·····		<u> </u>	<u> </u>					
			0	THER I	REFE	RENCES - NON PA	FENT LITE	RATURE DOCUM	IENTS		
Examir Initial		Cite No. 1	Includ (book, m	e name o agazine,	of the journ	al, serial, symposium,	catalog, etc.).	tle of the article (wh date, page(s), volu ere published.	nen appr me-issu	ropriate), title of the item e number(s), publisher, city	
		FA				Article " Genomics	of Vascula	ar Injury a Platf		or Rational Drug Design" ry-biotechelsinki03.pdf	
			i								
Examine	r		<u> </u>				Date Co	nsidered			

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIP Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Patent and Trademark Office: U.S. Department of Commerce Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

-Substitute fo	r form l	449A/PTO				Complete If Known				
INFO		ATION DISCLO IN AN APPL use as many shee	ICATIO	ON			·			
	(0	ise as many since	ts as nec	CSS	-	pplication Nu	umher	Ι		
						iling Date			· · · · · · · · · · · · · · · · · · ·	
					 	irst Named I	nventor	S Iav	yaraman	
						roup Art Unit		<u> </u>	, with the same and the same an	
					E	xaminer Name	e		• ***	
Sheet		2	of		8 A	ttorney Docke	et Number	795-4	A03-004	
	-				U.S. PATENT DOC	UMENTS	<u> </u>			
Examiner Initials	Cite No. 1	U.S. Patent Do Number	Coument Kind Co (if know		Name of Patentee or A Cited Docum		Date of Public of Cited Docu MM-DD-Y	ment	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	AW	5,688,824			Williams		11-18-19	97		
	ΑX	5,728,710			Luengo		03-17-19	98		
-	AY	5,837,313			Ding et al.	·	11-17-19	98		
	ΑZ	5,891,507			Jayaraman		04-06-19	98		
	BA	5,997,468			Wolff et al.		12-07-19	99		
	ВВ	6,046,328			Schonharting et al.		04-04-20	00		
	ВС	6,051,596			Badger		04-18-20	00		
	BD	6,071,305			Brown et al.		06-06-20	00		
	BE	6,129,705			Grantz		10-10-20	00		
	BF	6,143,037			Goldstein et al.		11-07-20	00		
	BG	6,153,252			Hossainy et al.		11-28-20	00		
	ВН	6,197,781			Guitard et al.		03-06-20	01		
	BI	6,203,551			Wu	,	03-20-20	01		
	BJ	6,231,600			Zhong		05-15-20	01		
· · · · · · · · · · · · · · · · · · ·	BK	6,238,430			Klumb et al.		05-29-20	01		
	BL	6,239,102			Tiemessen		05-29-20	01		
		6,239,124			Zenke et al.		05-29-20	01		
	L	6,245,104			Alt		06-12-20	01		
	!	6,248,127			Shah et al.		06-19-20			
	L	6,251,136			Guruwaiya et al.		06-26-20			
	BQ	6,254,634			Anderson et al.		07-03-20	01		
Examiner						Date Consi	dered			

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIP Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is

Patent and Trademark Office: U.S. Department of Commerce
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute fo	ORM	ATION DISCL IN AN APPL	ICAT	ION	ſ		Comp	olete If	Known
	(u	se as many shee	ts as n	ecess	sary)				
						Application N	umber		
						Filing Date			
						First Named I Group Art Uni		S. Ja	yaraman
						Examiner Nam			
Sheet		1	of		8	Attorney Dock		705	A03-004
Silect		•	01	<u> </u>	U.S. PATENT DO	<u> </u>	or runnoc.	193-	A03-004
Examiner Initials	Cite No. 1	U.S. Patent D Number	Kind	Code ²	Name of Patentee of	or Applicant of	Date of Public of Cited Docu MM-DD-Y	ment	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
Hittais		3,903,071	(II KI	,	Holmes	directi	09-02-19		riguies Appear
	AB	4,650,803			Stella et al.		03-17-19	87	
	AC	5,100,899			Calne		03-31-19	92	<u> </u>
-	AD	5,212,155			Calne		05-18-19	93	
	AE	5,221,740			Hughes	,	06-22-19	93	
	AF	5,282,785			Shapland et al.		02-01-19	94	
	AG	5,283,257			Gregory et al.		02-01-19	94	
		5,286,254			Shapland et al.		02-15-19	94	
		5,286,731			Caufield et al.		02-15-19		
	1	5,288,711			Mitchell et al.		02-22-19		
		5,308,847			Calne		05-03-19		
		5,318,895			Kahn et al.		06-07-19		
		5,403,833			Calne		04-04-19		·
	↓	5,457,113			Cullinan et al.		10-10-19		
	AO	5,461,058			Calne		10-24-19	95	
		5,496,832			Armstrong	<u> </u>	03-05-19		
	ــــــــــــــــــــــــــــــــــــــ	5,508,397			Or et al.		04-16-19	96	<u>.</u>
	AR	5,516,781			Morris et al.	·	05-14-19	96	
		5,519,042			Morris et al.		05-21-19		
		5,624,946			Williams		04-29-19		
		5,646,160			Morris et al.		07-08-19		
	AV	5,674,732			Nishida et al.		10-07-19	97	
Examine	r					Date Cons	idered		_

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIP Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Substitute for	or form 1449B/PTO			Compl te if Known				
		\ .	OL COURT	_Application Number				
INFOR	KIMATION L	JIS	CLOSURE	Filing Date				
STATI	EMENT RY	' Δ	PPLICANT	First Named Inventor	S. JAYARAMAN			
OIAII		-	I LIOAII	Group Art Unit				
	(use as many shee	ets a	s necessary)	Examiner Name				
Sheet	5	of	8	Attorney Docket Number	795-A03-004			

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
-	FB	D. BUNJES, C. HARDT, M WILLINGHOFF and, H WAGNER, CYCLOSPORIN A MEDIATES IMMUNOSUPRESSION OF PRIMARY CYTOTOXIC T CELL RESPONSES BY IMPAIRING THE RELEASE OF INTERLEUKIN 1 AND INTERLEUKIN 2, J. IMMUNOL. 1981, 11:657-661.	
	FC	J DIJOSEPH, E FLUHLER, J ARMSTRONG, M SHARR, and S SEHGAL, THERAPEUTIC BLOOD LEVELS OF SIROLIMUS (RAPAMYCIN) IN THE ALLOGRAFTED RAT, TRANSPLANTATION 1996, 62:1109-1112.	
	FD	B HAUSEN, K BOEKE, G BERRY, I BEGARRA, L BENET, U CHRISTIANS and R MORRIS, COADMINISTRATION OF NEORAL AND THE NOVEL RAPAMYCIN ANALOG, SDZ RAD, TO RAT LUNG ALLOGRAFT RECIPIENTS, TRANSPLANTATION 1999, 67:956-962.	
	FE	L TURKA, J DAYTON, G SINCLAIR, C THOMPSON, and B MITCHELL, GUANINE RIBONUCELEOTIDE DEPLETION INHIBITS T CELL ACTIVATION, J. Clin. Invest. 1991, 87:940-948.	
	FF	W SCHULER, R SEDRANI, S COTTENS, B HABERLIN, M SCHULZ, H SCHUURMAN, G ZENKER, H ZERWES, and M SCHREIBER, SDZ RAD, A NEW RAPAMYCIN DERIVATIVE, TRANSPLANTATION 1997, 64:36-42.	
***************************************	FG	H SCHUURMAN, J RINGERS, W SCHULER, W SLINGERLAND and M JONKER, ORAL EFFICACY OF THE MACROLIDE IMMUNOSUPPRESSANT SDZ RAD AND OF CYCLOSPORINE MICROEMULSION IN CYNOMOLGUS MONKEY KIDNEY ALLOTRANSPLANTATION, TRANSPLANTATION 2000, 69:737-742.	
	FH	J. SOUSA, A ABIZAID, A ABIZAID, F FERES, I PINTO, A SEIXAS, R STAICO, L MATTOS, A SOUSA, R FALOTICO, J JAEGER, J POPMA, P SERRUYS, M COSTA, LACK OF NEOINTIMAL PROFLIFERATION AFTER IMPLANTATION OF SIROLIMUS-COATED STENTS IN HUMAN CORONARY ARTERIES, CIRCULATION 2000, 102:r54-r57.	
	FI	C GREGORY, S KATZNELSON, S GRIFFEY, A KYLES and E BERRYMAN, FLUVASTATIN IN COMBINATION WITH RAD SIGNICANTLY REDUCES GRAFT VASCULAR DISEASE IN RAT CARDIAC ALLOGRAFTS, CIRCULATION 2001, 72:989-993.	
	FJ	R MORRIS, IMMUNOPHARMACOLOGY OF NEW XENOBIOTIC IMMUNOSUPRESSIVE MOLECULES, SEMINARS IN NEPHROLOGY 1992, 12:304-314.	
	FK	J MEHILLI, A KASTRATI, W KOCH, C BOTTIGER, N VON BECKERATH, A SCHOMIG, RELATION BETWEEN TUMOR NECROSIS FACTOR (TNF) GENE POLYMORPHISMS AND THROMBOTIC EVENTS AND RESTENOSIS IN PATIENTS WITH CORONARY STENTING, ABSTRACT FROM ACCIS 2000 MEETING, 13A.	
	FL	R. KNIGHT, M. FERRARESSO, F. SERINO, S. KATZ, R. LEWIS, AND B.D. KAHAN, LOW-DOSE RAPAMYCIN POTENTIATES THE EFFECTS OF SUBTHERAPEUTIC DOSES OF CYCLOSPORINE TO PROLONG RENAL ALLOGRAFT SURVIVIAL IN THE MONGREL CANINE MODEL, TRANSPLANTATION 1993, 55:947-949.	

Examiner		Date	
Signature	•	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for	or form 1449B/PTO			Complete if Known			
INICAC	NA A TION I	.	OL COURT	Application Number			
INFUR	KIMA HON I	JI5	CLOSURE	Filing Date			
STATI	EMENT RY	/ Δ	PPLICANT	First Named Inventor	S. JAYARAMAN		
O 17 11 1			I I LIOAIII	Group Art Unit			
	(use as many she	ets a	s necessary)	Examiner Name			
Sheet	6	of	8	Attorney Docket Number	795-A03-004		

		legisted name of the public (in CADITAL ACTION), the of the public (in the case) of the case of the ca	$\overline{}$
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	1
	FM	H SCHUURMAN, S COTTENS, S FUCHS, J JOERGENSEN, T MEERLOO, R SEDRANI, M TANNER, G ZENKE and W SCHULER, SDZ RAD, A NEW RAPAMYCIN DERIVATIVE, TRANSLANTATION 1997, 64:32-35.	
	FN	B KAHAN, M MURGIA, J SLATION, and K NAPOLI, POTENTIAL APPLICATIONS OF THERAPEUTIC DRUG MONITORING OF SIROLIMUS IMMUNOSUPPRESSION IN CLINICAL RENAL TRANSPLANTATION, THERAPEUTIC DRUG MONITORING 1995, 17:672-675.	
	FO	R YATSCOFF, P WANG, K CHAN, D HICKS and J ZIMMERMAN, RAPAMYCIN: DISTRIBUTION, PHARMACOKINTETICS, AND THERAPEUTIC RANGE INVESTIGATIONS, THERAPEUTIC DRUG MONITORING 1995, 17:666-671.	
	FP	H.U. SCHORLEMMER, F.R. SEILER, and R.R. BARTLETT, PROLONGATION OF ALLOGENEIC TRANSPLANTATION SKIN GRAFTS AND INDUCTION OF TOLERANCE BY LEFLUNOMIDE, A NEW IMMUNOSUPRESSIVE ISOXAZOL DERIVATIVE, TRANSPLANTATIONS PROCEEDINGS 1993, 25:753-767.	
	FQ	D BRANISTEANU, C MATHIEU, R BOUILLON, SYNERGISM BETWEEN SIROLIMUS AND 1,25 DIHYDROXYVITAMIN D, IN VITRO AND IN VIVO, JOURNAL OF NEUROIMMUNOLOGY 1979, 79:138-147.	
	FR	B KAHAN, EFFICACY OF SIROLIMUS COMPARED WITH AZATHIOPRINE FOR REDUCTION OF ACUTE RENAL ALLOGRAFT REJECTION: A RANDOMISED MULTICENTRE STUDY, LANCET 2000, 356:194-202.	
	FS	B KLUGHERZ, G LLANOS, W LIEUALLEN, G. KOPLA, G PAPANDREOU, P NARAYAN, T LEVENGOOD, B SASSEEN, S ADELMAN, R FALOTICO, R WILENEIR, STENT-BASED DELIVERY OF SIROLIMUS FOR THE PREVENTION OF RESTENOSIS, ABSTRACT FROM ACCIS 2000 MEETING.	
	FT	R SAUNDERS, M METCALFE, M NICHOLSON, RAPAMYCIN IN TRANSPLANTATION: A REVIEW OF EVIDENCE, KIDNEY INTERNATIONAL 2001, 59:3-16.	
	FU	R YATSCHOFF, D LeGATT, and N KNETEMAN, THERAPEUTIC MONITORING OF RAPAMYCIN: A NEW IMMUNOSUPRESSIVE DRUG, THERAPEUTIC DRUG MONITORING 1993, 15:478-482.	
	FV	S STEPKOWSKI, K NAPOLI, M WANG, X QU, T CHOU, and B KAHAN, EFFECTS OF THE PHARMACOKINETIC INTERACTION BETWEEN ORALLY ADMINISTERED SIROLIMUS AND CYCLOSPORINE ON THE SYNERGISTIC PROLONGATION OF HEART ALLOGRAFT SURVIVAL IN RATS, TRANSPLANTATION 1996, 62:986-994.	
	FW	B. HAUSEN, J. GUMMERT, G.J. BERRY, U.CHRISTIANS, N. SERKOVA, T. IKONEN, L. HOOK, F. LEGAY, W. SCHULER, M.H. SCHREIER, and R.E. MORRIS, PREVENTION OF ACUTE ALLOGRAFT REJECTION IN NONHUMAN PRIMATE LUNG TRANSPLANT RECIPIENTS, TRANSPLANTATION 2000, 69:488-496.	_

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Substitute fo	or form 1449B/PTO			Complete if Known			
NICOC	NA A TIONI F	NC	CI OCUDE	Application Number			
INFUR	KIVIA HON L	JIS	CLOSURE	Filing Date			
STATI	EMENT RY	' Δ	PPLICANT	First Named Inventor	S. JAYARAMAN		
01/11		•	LIOAN	Group Art Unit			
	(use as many shee	ets a	s necessary)	Examiner Name			
Sheet	7	of	8	Attorney Docket Number	795-A03-004		

Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the										
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) nublisher city and/or country where published	Т							
	FX	S SEHGAL, RAPAMUNE (SIROLIMUS, RAPAMYCIN): AN OVERVIEW AND MECHANISM OF ACTION, THERAPEUTIC DRUG MONITORING 1995, 17:660-665.								
-	FY	R MORRIS, MECHANISMS OF ACTION OF NEW IMMUNOSUPPRESIVE DRUGS, THERAPEUTIC DRUG MONITORING 1995, 17:564-569.								
	FZ	P KELLY, S GRUBER, F BEHBOD, and B KAHAN, SIROLIMUS, A NEW, POTENT IMMUNOSUPPRESSIVE AGENT, PHARMACOTHERAPY 1997, 17:1148-1156.								
	EA	G INGLE, T STEVENS, and C HOLT, SIROLIMUS: CONTINUING THE EVOLUTION OF TRANSPLANT IMMUNOSUPRESSION, THE ANNALS OF PHARMACOTHERAPY 2000, 34:1044-1055.	ļ							
·····	ЕВ	S MARX, A MARKS, BENCH TO BEDSIDE. THE DEVELOPMENT OF RAPAMYCIN AND ITS APPLICATION OF STENT RESTENOSIS, CIRCULATION 2001, 104:852-855.								
	EC	S.M. STEPKOWSKI and B.D. KAHAN, SYNERGISTIC ACTIVITY OF THE TRIPLE COMBINATION: CYCLOSPORINE, RAPAMYCIN, AND BREQUINAR, TRANSPLANTATION PROCEEDINGS 1993,24:29-31.								
	ED	B KAHAN, M MURGIA, J SLATON, and K NAPOLI, POTENTIAL APPLICATIONS OF THERAPEUTIC DRUG MONITORING OF SIROLIMUS IMMUNOSUPRESSION IN CLINICAL RENAL TRANSPLANTATION, THERAPEUTIC DRUG MONITORING 1995, 17:672-675.								
	EE	S SEHGAL, RAPAMUNE (RAPA, RAPAMYCIN, SIROLIMUS): MECHANISM OF ACTION IMMUNOSUPPRESSIVE EFFECT RESULTS FROM BLOCKADE OF SIGNAL TRANSDUCTION AND INHIBITION OF CELL CYCLE PROGRESSION, CLINICAL BIOCHEMISTRY 1998, 31:335-351.								
	EF	B KAHAN, J CHANG, S SEHGAL, PRECLINICAL EVALUATION OF A NEW POTENT IMMUNOSUPPRESSIVE AGENT, RAPAMYCIN, TRANSPLANTATION 1991, 52:185-191.								
	EG	O VILICKY, H ZOU, V MULLER, J LACHA, A SZABO and U HEEMANN, SDZ-RAD PREVENTS MANIFESTATION OF CHRONIC REJECTION IN RAT RENAL ALLOGRAFTS, TRANSPLANTATION 2000, 69:497-502.								
	EH	K NAPOLI AND B KAHAN, HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY OF RAPAMYCIN, CLINICAL CHEMISTRY 1991, 37:294-295.								

Examiner	Date	
Signature	 Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute f	or form 1449B/PTO			Complete if Known				
INITOT	SAATION!	DIC	OL OCUPE	Application Number				
INFOR	KIVIATION	DI2	CLOSURE	Filing Date				
STAT	FMFNT R	Υ Δ	PPLICANT	First Named Inventor	S. JAYARAMAN			
			LIOAN	Group Art Unit				
	(use as many she	ets a	s necessary)	Examiner Name				
Sheet	8	of	8	Attorney Docket Number	795-A03-004			

			_
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), nublisher, city and/or country where published	-
	EI	Henderson, D.J., I. Naya, R. V. Bundick, G.M. Smith and G. A. Schmidt. 1991. Comparison of the effects of FK-506, Cyclosporin-A, and rapamycin on IL-2 production. Immunology 73: 316.	
	EJ	Vathsala, A., T.C. Chou, B.D. Kahan. 1990. Analysis of the interactions of immunosuppressive drugs with cyclosporine in inhibiting DNA proliferation. Transplantation 49: 463.	
	EK	Kahan B.D., S. Gibbons, N. Tejpal, S.M. Stepkowski, and T.C. Chou. 1991. Synergistic interactions of cyclosporine and rapamycin to inhibit immune performances of normal human peripheral blood lymphocytes in vitro. Transplantation 51: 232.	
	EL	Tu Y, Stepkowski SM, Chou TC, Kahan BD. The synergistic effects of cyclosporine, sirolimus and brequinar on heart allograft survival in mice. Transplantation 1995; 59: 177.	
	EM	Martin DF, DeBarge LR, Nussenblatt RB, Chan CC, Roberge FG. Synergistic effect of rapamycin and cyclosporin A in the treatment of experimental autoimmune uveoretinitis. J Immunol 1995; 154: 922.	
	EN	Yakimets WJ, Lakey JR, Yatscoff RW, et al. Prolongation of canine pancreatic islet allograft survival with combined rapamycin and cyclosporine therapy at low doses: rapamycin efficacy is blood level related. Transplantation 1993; 56: 1293.	
	EO	Gregory CR, Huang X, Pratt RE, et al. Treatment with rapamycin and mycophenolic acid reduces arterial intimal thickening produced by mechanical injury and allows endothelial replacement. Transplantation. 1995; 59: 655-661.	
	ЕP	Gallo R, Padurean A, Jayaraman T, et al. Inhibition of intimal thickening after balloon angioplasty in porcine coronary arteries by targeting regulators of cell cycle. Circulation, 1999; 99: 2164-2170.	
	EQ	REDDY, KR, Controlled-Release, Pegylation, Liposomal Formulations: New Mechanisms in the Delivery of Injectable Drugs, The Annals of Pharmacotherapy, Vol 34, pp 915-923, July/August 2000	
And the second s	ER	M. GUBA et al., Rapamycin inhibits primary and metastatic tumor growth by antiangiogenesis: involvement of vascular endothelial growth factor, Nature Medicine, Volume 8, February 2002, pp 128-135.	
· · · · · · · · · · · · · · · · · · ·	ES	M. IURLARO et al., Antiangiogenesis by cyclosporine, Experimental Hematology, Volume 26, 1998, pp. 1215-1222.	-

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/99. OMB 0651-0031 Patent and Trademark Office: U.S. Department of Commerce

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO						Complete If Known				
INFORMATION DISCLOSURE STATEMENT						Complete If Known				
IN AN APPLICATION (use as many sheets as necessary)										
(use as many sneets as necessary)					,u1 y)	Application Number		<u> </u>		
						Filing Date				
								yaramna		
						Group Art Unit				
					•	Examiner Name				
Sheet		3.	of		8	Attorney Docket Number		795-A03-004		
					U.S. PATENT DO	CUMENTS				
Examiner	Cite	U.S. Patent Do	ocument Kind (Code ² Name of Patentee o		ar Annlicant of	Date of Public		Pages, Columns, Lines, Where Relevant Passages or Relevant	
Initials	No. 1	Number	(if kno				of Cited Document MM-DD-YY		Figures Appear	
	BR'	6,258,121	i		Yang et al.		07-10-2001			
	BS	6,273,913			Wright et al.		08-14-2001			
		6,299,604			Ragheb	ıeb		01		
	BU	6,309,380			Larson		10-30-2001		•	
	BV	6,335,029			Kamath et al.		01-01-2002			
	BW	6,344,035			Chudzik et al.		02-05-2002			
	BX	6,364,903			Tseng et al.		04-02-2002			
	BY	6,368,658 ·			Schwartz et al.	-	04-09-2002			
	BZ	6,379,382			Yang		04-30-2002			
	CA	6,455,518			Zenke et al		09-24-2002			
		6,530,951			Bates		03-11-2003			
	↓	6,545,097			Pinchuk		04-08-2003			
	CD	6,585,764			Wright et al.		07-01-2003			
			·							
					FOREIGN PATE	ENT DOCUMEN	NTS			
Examiner Initials	Cite No.	Foreign Patent Document Cite No. Office Number (if known)			Name of Patentee or Applicant of Ci Document		Date of Publication of Cited Document MM-DD-YY		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	DA	WO 98/55162 A2			Polybiomed Ltd.		12-10-1998			
	DB	WO 98/18468 A1		American Home Products		05-07-1998				
	DC	WO 98/074	415 A2		Novartis AG		02-26-	1996		
	DD	W0 96/049	06 A1		Wellcome Found	ation Ltd.	02-22	1996		
Examine	r					Date Consi	dered			

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIP Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ³ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is